Medical Product Alert on Unauthorized Fluphenazine Decanoate (Flyzox) 25mg/ml Injection.Medical Product Alert 08/2025

Alert Summary

The Ethiopian Food and Drug Authority is mandated by Article 38 of the Food and Medicine Administration Proclamation No. 1112/2019 to perform periodic monitoring of the safety, quality, and efficacy of medicines through surveillance.

The Authority has identified a product quality defect of Fluphenazine Decanoate Injection (Flyzox) 25 mg/ml. In response, the Authority reviewed the complaint, conducted an investigation, and carried out market surveillance to confirm the product's circulation in the market. The investigation report revealed that the product is unauthorized for marketing as a medicinal product within the country.

Brief Description of the Product

- **Product Name**: Fluphenazine Decanoate injection (Flyzox) 25mg/ml injection.
- **Batch Number**: 403,
- **Manufacturing date**: 06/2024
- **Expire Date:** 05/2026
- **Stated manufacturer**: Care win pharmaceuticals (Guj) Pvt. Ltd. India and
- **Marketed by**: DELLWICH LIFESCIENCE LLP

Risk Summary

The unauthorized Fluphenazine Decanoate (Flyzox) 25mg/ml injection should not be used for treatment of schizophrenia and other psychotic disorders.

How to Identify this Unauthorized Product

The product's market authorization status was verified by searching the eRIS database and contacting the Medicine Evaluation and Market Authorization Lead Executive Office for confirmation.

Target Audiences

- **Healthcare Professionals**

The authority intends to alert health care providers about the need to detect and remove circulation and administration/use of **unauthorized** Fluphenazine Decanoate injection (Flyzox) 25mg/ml to prevent harm to patients.

- **Advice to Regional Regulatory Bodies**

The Authority also intends to alert regional regulatory bodies to strengthen monitoring of the circulation and use of unauthorized and substandard products.

- **Public Advice**

If you are in possession of this unauthorized and substandard product, please do not use it. If you or anyone you know has used this product or experienced any adverse reaction following its use, you are advised to seek immediate medical attention from a qualified healthcare professional.

Report Adverse Events

The EFDA encourage members of the public and health care provider to report all suspicious, substandard and falsified medicinal products to the Ethiopia Food and Drug Authority through, ADE reporting form, Med safety mobile apps available at play store for androids and app store for iPhone, E-reporting available on EFDA website (www.efda.gov.et), through email pharmacovigilance@efda.gov.et and toll-free number 8482.

Picture of Unauthorized Product